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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/346,479	07/01/1999	ANDREW J. RITTER	4806-2	2480

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ANDREW J. RITTER
11778 STONEHENGE LANE
LOS ANGELES, CA 90077

EXAMINER
COE, SUSAN D

ART UNIT	PAPER NUMBER
1651	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/346,479	Applicant(s) RITTER, ANDREW J.	
	Examiner Susan Coe	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *6 & 10* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 25-48 are currently pending.

Continued Prosecution Application

The request filed on September 21, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/346,479 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (Journal of Dairy Science (1983), vol. 66, pp. 959-966).

The claims are drawn to a method of reducing lactose intolerance by administering a lactose product concurrently with a fermented dairy product that contains live bacteria.

Kim teaches that administering milk with added *Lactobacillus acidophilus* increases lactose tolerance in subjects that are lactose intolerant. The subjects consuming the milk with added *L. acidophilus* showed a large improvement in the toleration of lactose (see Table 2 on page 962 and Table 3 on page 963).

From applicant's remarks filed December 29, 2000, it appears that the lactose containing product and the fermented product containing the bacteria are intended to be different products. However, the claims do not clearly reflect this limitation. Milk is a lactose containing product; thus, drinking milk with live bacteria is considered to anticipate the claims because the lactose is being administered with the fermented dairy product. The milk is fermented by the *L. acidophilus* cultures.

3. Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Onwulata (Am. J. Clin. Nutr. (1989), vol. 49, pp. 1233-1237).

The claims are drawn to a method of reducing lactose intolerance by administering a lactose product concurrently with a fermented dairy product that contains live bacteria.

Onwulata teaches that administering yogurt increases lactose tolerance in lactose intolerant individuals. The yogurt contained live culture of *L. bulgaricus* and *S. thermophilus*. Therefore, Onwulata shows that it was known in the art at the time of the invention that administering bacteria in conjunction with a lactose containing product, yogurt, increased lactose tolerance.

From applicant's remarks filed December 29, 2000, it appears that the lactose containing product and the fermented product containing the bacteria are intended to be different products. However, the claims do not clearly reflect this limitation. Yogurt is a lactose containing product; thus, eating yogurt with live bacteria is considered to anticipate the claims because the lactose is being administered with the fermented dairy product.

4. Claims 25-28, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Martini et al. (Am. J. Clin. Nutr. (1991), vol. 53, pp. 1253-1258).

Martini teaches a method of reducing lactose intolerance by administering yogurt with additional lactose or milk (see page 1254, first column, second paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 25 and 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Dairy Science (1983), vol. 66, pp. 959-966).

As stated above, Kim teaches that administering milk with added *Lactobacillus acidophilus* increases lactose tolerance in subjects that are lactose intolerant. However, Kim does not teach administering *L. acidophilus* and milk using the regimen claimed by applicant.

The treatment regimen used to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

6. Claims 25, 29-31, and 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onwulata et al. (Am. J. Clin. Nutr (1989), vol. 49, pp. 1233-1237).

As stated above, Onwulata teaches that administering yogurt increases lactose tolerance in lactose intolerant individuals. The yogurt contained live culture of *L. bulgaricus* and *S. thermophilus*. Therefore, Onwulata shows that it was known in the art at the time of the invention that administering bacteria in conjunction with a lactose containing product, yogurt, increased lactose tolerance. However, Onwulata does not teach administering yogurt using the regimen claimed by applicant.

The treatment regimen used to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

Allowable Subject Matter

7. The following claims, drafted by the examiner and considered to distinguish patentably over the art of record in this application, claims 49-55 are presented to applicant for consideration: --

49. A method for increasing lactose tolerance in a subject experiencing lactose intolerance comprising the steps of:

a) administering a first dosage of a lactose containing product to the subject each day for a first predetermined number of days,

wherein said first predetermined number of days is 42 days, and

wherein said first dosage comprises administering either about 1 tablespoon of milk or about 0.8 grams of lactose powder for days 1 to 3 of said first predetermined number of days;

b) administering a pharmaceutically effective amount of live cultured bacteria to the subject each day in conjunction with the administration of said first dosage, the administration of the live cultured bacteria commencing on the first day of said first predetermined number of days and continuing for two days;

c) increasing said first dosage over the course of said first predetermined number of days, said first dosage increasing at a rate of 1 additional tablespoon of milk or about 0.8 additional grams of lactose powder for each day beginning with day 4 of said first predetermined number of days such that by about day 18 of said first predetermined number of days said first dosage is about 16 tablespoons of milk or about 12.8 grams of lactose powder;

d) administering a second dosage of the lactose containing product to the subject each day starting at day 19 of said first predetermined number of days,

wherein said second dosage comprises about 1 tablespoon of milk or about 0.8 grams lactose powder; and

e) increasing said second dosage over the course of said first predetermined number of days,

wherein said second dosage increases at a rate of about 1 additional tablespoon of milk or about 0.8 additional grams of lactose powder for each day such that by about day 34 of said first predetermined number of days said second dosage is about 16 tablespoons of milk or about 12.8

grams of lactose powder, said second dosage being administered at a time of the day other than when said first dosage is administered.

50. The method set forth in claim 49, wherein said lactose powder is in capsule form.

51. The method set forth in claim 49, further comprising:

f) discontinuing administration of the first and second dosages at day 35 of said first predetermined number of days; and

g) administering to the subject a third dosage of a lactose containing product in a predetermined amount twice a day beginning at said day 35 and continuing for the remainder of said first predetermined number of days,

wherein said third dosage comprises about 9 ounces of milk, said third dosage increasing at a rate of 1 ounce of milk each day for three days such that on about day 38 of said first predetermined number of days said third dosage comprises about 12 ounces of milk.

52. The method set forth in claim 51, further comprising discontinuing the administration of said third dosage on about day 39 of said first predetermined number of days and administering about 1 or 2 ounces of cheese for two days thereafter with dinner.

53. The method set forth in claim 51, wherein the dosages of the lactose containing products are administered without meals.

54. The method set forth in claim 51, wherein the dosages of the lactose containing products are administered in conjunction with meals.

55. The method set forth in claim 54, wherein the administration of said first dosage is performed with dinner, the administration of said second dosage is performed with breakfast, and the administration of said third dosage is performed with both breakfast and dinner.

--.

8. These claims are the same claims that were presented to applicant by the examiner in a proposed examiner's amendment faxed to the applicant on August 30, 2001. At that time, applicant refused entry of the amendment and chose to file a CPA to keep prosecution alive. With further consideration by the examiner, only these proposed claims are considered allowable because the closest prior art, Martini et al., teaches that administering a fermented lactose containing product with an additional lactose containing product does not increase the amount of lactose tolerance (see page 1256, top of first column). Therefore, as the claims are currently written, the prior art shows that the claimed method will not work to increase lactose tolerance over known methods. Applicant's specification has only shown that the method of increasing lactose tolerance is successful when administered in specific dosages that are reflected in the proposed claims (see specifically pages 9-12 of the specification). Therefore, the claims must reflect the dosages in order to claim a method that is shown to improve over what is taught in the prior art.

Conclusion

This is a CPA of applicant's earlier Application No. 09/346,479. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of $160.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing , whichever is longer, of an amendment after

final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

9. No claims are allowed; however, the claims indicated above are considered allowable and can be entered into the application with applicant's permission.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
November 27, 2001

FRANCISCO PRATS
PRIMARY EXAMINER